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Application Number	10/828,630
Filing Date	04/09/2004
First Named Inventor	Jill E. Parker
Art Unit	1645
Examiner Name	Mark Navarro
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ENCLOSURES *(check all that apply)*

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- ☐ Fee Attached
- Amendment / Reply
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The fee (37 CFR 41.20(b)(2)) for this Appeal Brief is $500. The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.

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SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

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Signature: Paul D Heydon

Typed or printed name: Paul D. Heydon Date: 1 March, 2006

Application No.: 10/828,630
Appeal Brief

Applicants: Jill E. Parker et al.
Filed: 04/09/2004
Title: Curlicue Vaccine Strain of Bacillus Anthracis
T.C./Art Unit 1645
Examiner: Mark Navarro
Docket No.: AFD 503
Customer No.: 26902
Confirmation No.: 5340

Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

Appeal Brief

Sir:

In response to the Office Action (Final Rejection) of October 6, 2005, and in connection with the Notice of Appeal filed on January 5, 2006, the Assignee (Secretary of the Air Force) respectfully submits the following Appeal Brief.

Real party in interest.

The Secretary of the Air Force is the real party in interest.

Related appeals and interferences.

None.

Status of claims.

Claims 1-4 are on appeal.

Claim 1 is rejected.

Claim 2 is refused for some reason not fully and clearly stated.

Claims 3-4 are rejected.

Claims 5-10 are withdrawn, affected by a restriction requirement. The examiner required restriction to Claims 1-4, and withdrew new Claims 5-10 from consideration, "as being directed to a non-elected invention."

Status of amendments.

No amendment was filed subsequent to final rejection.

Summary of claimed subject matter.

The subject matter relates generally to the disease of anthrax and, more particularly, to a novel strain of Bacillus anthracis having unique characteristics that are important in designing a vaccine. See Specification Paragraph [0003] and Specification Paragraph [0022], Page 9, Line 7.

Claim 1: A vaccine strain of Bacillus anthracis. See Specification Paragraph [0021] Page 8, Lines 9-16 and Paragraph [0032] Page 12, Lines 18-22.

Claim 2: A mutated strain of Bacillus anthracis. See Specification Paragraph [0030] Page 11, Lines 8-12 and Paragraph [0031] Page 12, Lines 3-17.

Claim 3: A mutated strain of Bacillus anthracis having physicochemical properties comprising thermal resistance, among other things. See Specification Paragraph [0031] Page 12, Lines 3-17 and Paragraph [0046] Page 18, Lines 6-20.

Claim 4: The strain of claim 3, further comprising the physicochemical property of producing delayed onset of death in a laboratory animal. See Fig. 5. See Specification Paragraph [0049] Page 19, Line 23 - Page 20, Line 2.

Grounds of rejection to be reviewed on appeal.

Claim 1 stands rejected under 35 U.S.C. 112, first paragraph, as failing to

comply with the enablement requirement.

Claim 2 is refused for some reason not fully and clearly stated.

Claims 3-4 stand rejected under 35 U.S.C. 102, as being anticipated by Ivins, US Pat. No. 6,387,665, and Keim, US Patent Application 20020055628A1.

Argument.

Claim 1

The assignee respectfully asserts that it was erroneous to reject Claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. A prima facie case of nonenablement has not been established.

A) "When rejecting a claim under the enablement requirement of § 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification ..." In re Wright, 999 F.2d 1557, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). As stated in MPEP 2164.04, "the examiner has the initial burden ... [Citing *In re Wright*] ... examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled..." The Final Rejection has failed to provide a reasonable explanation directed to the scope of rejected Claim 1 in this case, considering the claim language: a "vaccine strain." The Final Rejection is improperly based on only one word taken from Claim 1: "vaccine." This one word is improperly treated

as if it were a red flag that prevents patenting. See Final Rejection Page 4, Line 4 and Page 5, Line 21. Also note the contrast between Claim 1's language, "vaccine strain," and the claims to a "vaccine" found not enabled in *Wright*.

B) "Title 35 requires only that the inventor enable one of skill in the art to make and use the full scope of the claimed invention... Thus, the level of disclosure necessary to satisfy section 112 of title 35 varies according to the scope of the claimed invention." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003). Also, "few patented inventions are an immediate commercial success. Rather, most inventions require further development to achieve commercial success. Thus, additional inventive work does not alone show nonenablement." *CFMT*, 68 USPQ2d at 1946. As stated in MPEP 2164, "to comply with 35 U.S.C. 112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect' [Citing *CFMT*]."

The Final Rejection's insistence on prevention is an improper insistence on enabling a perfected, commercially viable embodiment. It is improper because Claim 1 does not describe a perfected, commercially viable embodiment. Claim 1 should be read in light of the following material in the Specification for example: a new strain, having "unique characteristics that are important in designing a vaccine..." Specification Paragraph [0022], Page 9, Line 7. Also

consider: "a vaccine strain of Bacillus anthracis *from which may be produced* an improved anthrax vaccine ... a vaccine strain of Bacillus anthracis that will *enable identification of new genes* that contribute to the pathogenesis of the organism and thereby elucidate new antigens that play a role in eliciting a specific, protective immune response early in the infection process." Specification Paragraph [0021] Page 8, Lines 9-16 [emphasis added]. "A genetic fingerprint comparison of the mutant Alls/Gifford with the paternal Sterne strain should reveal the altered genes of the mutant. The protein products of the altered genes found by comparison to Sterne *could form the basis for a vaccine* that would stimulate antibody to inhibit the bicarbonate/CO2/heat- stimulated growth of anthrax that is necessary for its development in the host." Specification Paragraph [0032] Page 12, Lines 18-22 [emphasis added].

C) As stated in MPEP 2164.04, "References should be supplied if possible to support a prima facie case of lack of enablement ..." In this case however, the Final Rejection has not supplied a reference that supports a prima facie case of lack of enablement. The published application of Simonson, 20030143636A1, cited by the Final Rejection, is not relevant to the language of rejected Claim 1. The Simonson reference does not contain the phrase "vaccine strain" that is used in Claim 1. Simonson discusses studies of a perfected, commercially viable product: "the anthrax vaccine currently used for patients," known as the Anthrax Vaccine Adsorbed (AVA). See Simonson Paragraphs [0031] and [0034]-[0050], a section called "Animal Models and

Anthrax Strains." A quote from this section of Simonson is used in the Final Rejection. It is not relevant to rejected Claim 1. Again, the Final Rejection improperly insists on enabling a perfected, commercially viable embodiment.

Claim 2

The Final Rejection fails to state a definite ground for objecting to or rejecting this claim. There is only a hypothetical, conditional ground for an objection, "should claim 1 be found allowable," which has not happened. The stated ground has no relevance in this case, because the condition has not occurred (Claim 1 was not found allowable). A prima facie case for refusing Claim 2 has not been established.

Examiners "must state clearly and specifically" the prima facie case concerning patentability, and "give the applicant fair opportunity" to meet it. The concept of the prima facie case "serves to level the playing field and reduces the likelihood of administrative arbitrariness." *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) (Plager, J., concurring). Stating a conditional ground for an objection in the present case, where the condition has not occurred, does not meet the requirement for clearly and specifically stating the prima facie case against patentability of Claim 2. The Final Rejection in this case does not give the applicants a fair opportunity to confront the case against patentability of Claim 2.

"Where a claim is refused for any reason relating to the merits thereof it

should be "rejected" and the ground of rejection fully and clearly stated... The examiner should designate the statutory basis for any ground of rejection by express reference to a section of 35 U.S.C..." MPEP 707.07(d). In making a final rejection, "the examiner shall repeat or state all grounds of rejection ... clearly stating the reasons ..." 37 CFR § 1.113. In the present case, one might assume that there is an unstated issue of enablement concerning Claim 2, because the Final Rejection questions enablement concerning Claim 1, and the Final Rejection notes a similarity between Claims 1 and 2. A prima facie case of nonenablement has not been established concerning Claim 2 (see reasons provided above in response to the 35 U.S.C 112 first paragraph rejection of Claim 1.) Claim 2 apparently is refused for some reason relating to the merits, but the ground of rejection is not fully and clearly stated. A prima facie case for rejection of Claim 2 has not been established.

At least that portion of an examiner's so-called "objection" concerning "the correspondence of the specification to the statutory requirements" (e.g. enablement) is within the Board's jurisdiction. See *Ex parte C*, 27 U.S.P.Q.2d 1492, 1494 (BPAI 1992). The Assignee respectfully requests that the Board reverse the disposition of Claim 2.

Claim 3

It was erroneous to reject Claim 3, under 35 U.S.C. 102, as being anticipated by Ivins, US Pat. No. 6,387,665, and Keim, US Patent Application 20020055628A1. A prima facie case of anticipation has not been established.

As stated in MPEP 2131, to anticipate a claim, a reference must teach every element of the claim. In this case however, the Final Rejection has not supplied a reference that teaches every element of the claim. For example, this limitation in the rejected claim is not described in either of the references relied upon: thermal resistance. The Examiner's references do not mention thermal resistance. The Final Rejection points to sections of the references that merely describe various strains of Bacillus anthracis. Thus a prima facie case of anticipation has not been established.

Claim 4

It was erroneous to reject Claim 4, under 35 U.S.C. 102, as being anticipated by Ivins, US Pat. No. 6,387,665, and Keim, US Patent Application 20020055628A1. A prima facie case of anticipation has not been established. As stated in MPEP 2131, to anticipate a claim, a reference must teach every element of the claim. In this case however, the Final Rejection has not supplied a reference that teaches every element of the claim. This limitation in the rejected claim is not described in either of the references relied upon: delayed onset of death in a laboratory animal. The Examiner's references do not mention delayed onset of death. Again the Final Rejection points to sections of the references that merely describe various strains of Bacillus anthracis. Thus a prima facie case of anticipation has not been established.

For the complete claim language involved in the appeal, please see the attached Claims Appendix. (Neither an evidence appendix nor a related

proceedings appendix is applicable, so they are not attached.)

Conclusion

For the reasons advanced above, the Assignee respectfully contends that each claim is patentable, and requests the reversal of the Final Rejection.

Respectfully submitted,

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Attachment: Claims Appendix.

Claims appendix.

This appendix contains a copy of the claims involved in the appeal:

1. A vaccine strain of Bacillus anthracis which is the strain of Bacillus anthracis having deposit accession number ATCC PTA-3162.

2. A mutated strain of Bacillus anthracis which is the strain of Bacillus anthracis having deposit accession number ATCC PTA-3162.

3. A mutated strain of Bacillus anthracis having physicochemical properties comprising:

presence of pX01 plasmid;
synthesis of Diazoluminomelanin;
sensitivity to Penicillin;
ability to be lysed by Cherry gamma phage;
non-hemolytic;
production of nitrite from nitrate; and,
thermal resistance up to about 240 degrees C.

4. The mutated strain of claim 3, further comprising the physicochemical property of producing delayed onset of death in a laboratory animal, compared to the Sterne strain of Bacillus anthracis.